Appl. No. 09/825,423 Patent Case: ID01152

Response dated December 14, 2005 Reply to Office Action of June 14, 2005

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### **REMARKS**

### INFORMATION DISCLOSURE STATEMENT

An information disclosure statement which lists the title of each of the references is submitted herein.

### AMENDMENTS TO THE SPECIFICATION

The specification has been amended to recite "Hepatitis C Virus NS3 Helicase Subdomain I" as the title so as to more accurately reflect the presently claimed subject matter.

The specification has also been amended to reflect that U.S. Provisional Application No. 60/194,419 from which priority is claimed was filed on April 4, 2000. The Declaration originally submitted with this application as filed correctly recited the correct filing date. Note that the Office Action mailed on June 14, 2005 stated that the provisional application was filed on April 3, 2001.

In addition, the specification has been amended to reflect that the terms "SUPERDEX," "QUIKCHANGE," and "REBETRON" used herein are trademarks as well as the generic terminology used for these trademarks.

Page 26, lines 27-28 and page 42, line 4 have been amended to remove the reference to SEQ ID NO: 3. Of note, SEQ ID NO: 3 consists of 4 amino acids at the N-terminus linked to Ser<sub>181</sub>-Thr<sub>324</sub> of HCV NS3 helicase.

With regard to the sequence rules, the specification has been amended to reflect that amino acid sequence SDGK recited therein is SEQ ID NO: 2. In addition, the specification has been amended to reflect that the sequence listed in Table 5 is SEQ ID NO: 17, (*i.e.*, residues 181-324 from HCV NS3 helicase subdomain I). Notably, the sequence listed in Table 2 is described on page 38, lines 25-26 as being HCV NS3 helicase subdomain IIΔ SEQ ID NO: 4. A substitute sequence listing is also submitted herewith.

#### STATUS OF THE CLAIMS

Claims 1-5 and 7-17 are pending and have been amended. Support for these claim amendments can be found throughout the specification and in the originally filed claims. Of note, Claim 9 has been amended to remove the recitation of SEQ ID NO: 4 which is non-elected subject matter. Applicants reserve all rights to prosecute any subject matter removed by the present amendments in a subsequent divisional or continuation application.

### CLAIM OBJECTION – 37 CFR §1.75(c)

Claims 3-5, 7, 8, 12, and 13 are object to under 37 CFR §1.75(c) as being of improperly dependent form for failing to further limit the subject matter of a previous claim. Claims 3-5, 7, 8, 12, and 13 have been amended as detailed above. These amendments are believed to overcome this objection.

### CLAIM REJECTIONS - 35 USC §112, second paragraph

Claims 1-5, 7-10, 16, and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the abbreviation "HCV."

Claim 1 has been amended to remove the term "HCV." In addition, Claims 16, and 17 have been amended to replace the term "HCV" with the phrase "hepatitis C virus (HCV)." These amendments are believed to overcome this rejection of independent Claims 1, 16, and 17 as well as dependent Claims 2-5, 7, 8, and 10 (which depend on Claim 1). Of note, Claim 9 does not recite the abbreviation "HCV." As such, this rejection does not appear to be applicable to Claim 9.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of "an" HCV helicase protein rather than "the" HCV helicase protein.

Claim 1 has been amended to remove the phrase "an HCV helicase protein. This amendment is believed to overcome this rejection of independent Claim 1 as well as dependent Claims 2-5, 7, 8, and 10 (which depend on Claim 1). Of note, Claim 9 does not recite the rejected subject matter. As such, this rejection does not appear to be applicable to Claim 9.

Claims 1-5, 7, 8, 10, and 11-13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the phrase "derived from."

Claims 1 and 11 have been amended to remove the phrase "derived from." These amendments are believed to overcome this rejection of independent Claims 1 and 11 as well as dependent Claims 2-5, 7, 8, and 10 (which depend on Claim 1), and Claims 12 and 13 (which depend on Claim 11).

Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the phrase "structurally sound."

Claim 1 has been amended to remove the phrase "structurally sound." This amendment is believed to overcome this rejection of independent Claim 1 as well as dependent Claims 2-5, 7, 8, and 10 (which depend on Claim 1).

Claims 3-5, 7, 8, 12, and 13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for not reciting a "SEQ ID NO."

Claims 3-5, 7, 8, 12, and 13 have been amended to refer to specific SEQ ID NOs:. These amendments are believed to overcome this rejection of independent Claims 3-5, 7, 8, 12, and 13.

Claims 4, 5, 12, and 13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the phrase "derived from" with regard to polypeptides having particular amino acid substitutions and those without amino acid substitutions.

Claims 4, 5, 12, and 13 have been amended to refer to specific SEQ ID NOs: and no longer recite the phrase "derived from." These amendments are believed to overcome this rejection of independent Claims 4, 5, 12, and 13.

Claims 11-13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the phrase "subdomain I."

Claim 11 has been amended to remove the phrase "subdomain I." This amendment is believed to overcome this rejection of independent Claim 11 as well as dependent Claims 12 and 13 (which depend on Claim 11).

Claim 15 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of "A crystalline composition comprising ... structural coordinates."

Claim 15 has been amended to include the phrase "an isolated polypeptide described by" after the phrase "A crystalline composition comprising." This amendment is believed to overcome this rejection of Claim 15.

Claim 16 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the phrase "a buffer for a precipitant solution."

Claim 16 has been amended to replace the phrase "a buffer for a precipitant solution" with the phrase "a buffer for the precipitant solution." This amendment is believed to overcome this rejection of Claim 16.

Claims 16 and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of the term "about."

Claims 16 and 17 have been amended to remove the term "about." These amendments are believed to overcome this rejection of Claim 16 and 17.

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## CLAIM REJECTIONS - 35 U.S.C. § 112, first paragraph

Claims 1-5, 7, 8, 10-13, 16, and 17 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 11-15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 1-5, 7, 8, and 10-13 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claims 11-15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claim 16 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

In light of the claim amendments detailed above, the aforementioned 35 U.S.C. § 112, first paragraph rejections are believed to be overcome.

### CLAIM REJECTIONS - 35 USC §101

Claims 1-5, 7, 8, 10-13, and 15 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Support for this amendment is found in the specification, *e.g.*, at page 17, line 15.

Claims 1, 11, and 15 have been amended to recite the phrase "an isolated polypeptide." This amendment is believed to overcome this rejection of Claims 1, 11, and 15.

### CLAIM REJECTIONS - 35 USC §102

Claims 1-5, 7, 8, 10-13, and 16 are rejected under 35 U.S.C. §102(a) as being anticipated by Benz et al. (Benz et al., "Crystal structure of the ATPase domain of translation initiation factor 4A from Saccharomyces cerevisiae – the prototype of the DEAD box protein family," Structure Fold Des, 7(6):671-679 (1999) as evidenced by PGPUBS 20040253577.

In contrast to Benz *et al.* which describes a crystal structure of eIF4A, the present invention recites specific polypeptides that differ from those disclosed by Benz *et al.* As such, Claims 1-5, 7, 8, 10-13, and 16 are not anticipated by Benz *et al.* 

Claims 11-13 are rejected under 35 U.S.C. §102(b) as being anticipated by Kim et al. (Kim et al., "Hepatitis C virus NS3 RNA helicase domain with a bound oligonucleotide: the crystal structure provides insights into the mode of unwinding," Structure, 6:89-100 (1997)).

Kim *et al.* discloses a HCV NS3 helicase fragment that encompasses the C-terminal 465 amino acids of the 631-residue HCV NS3 protein with four additional mutations Ser332 to Pro, Asn403 to Ser, Ser410 to Ala, and Met505 to Thr.

Claims 11-13 have been amended to recite specific polypeptides that differ from those disclosed by Kim *et al.* Notably, the claimed polypeptides include an amino acid corresponding to Asn403 of the HCV NS3 protein. As such, Claims 11-13 are not anticipated by Kim *et al.* 

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# **CONCLUSION**

It is believed that the foregoing amendments and arguments place this application now in condition for allowance. Therefore, favorable action allowing pending Claims 1-5 and 7-17 is respectfully solicited.

Respectfully submitted,

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